REMARKS

Summary of the Office Action

Claims 1, 3, 5, 6, 8-15 and 18-20 are pending in this application.

Claim 11 is withdrawn as being directed to a non-elected species.

Claims 1 and 3 have been rejected as anticipated by Valley et al. U.S. Patent No. 5,814,016 ("Valley").

Claim 10 has been rejected as obvious over Valley in view of Stevens et al. U.S. Patent No. 5,916,193 ("Stevens").

Claims 1, 3, 5, 6 and 10 have been rejected for obviousness-type double patenting over U.S. Patent No. 6,423,032 ("the '032 patent")(which matured from the parent application of the present application).

Claims 2/1, 8/1, 12-15, 19 and 20 have been rejected for double patenting, 35 U.S.C. §101, over claims 1, 8, 15-17 and 19-21 of the '032 patent.

Applicants' Response

Applicant has canceled apparatus claims 1-11 without prejudice.

Applicant has amended the pending method claims, and added additional method claims, to patentably distinguish over the prior art of record. Applicant submits that the claims, as amended, also are separately patentable over the claims of the '032 patent, thus obviating the §101 double-patenting rejection. Applicant provides herewith a terminal disclaimer with respect to the '032 patent to obviate any obviousness-type double-patenting concerns with respect to the '032 patent.

Claim 12 has been amended to recite steps of inserting a catheter into the common carotid artery proximal of the bifurcation to the internal and external carotid arteries, expanding an occlusion device within the artery to reverse flow from the external artery, passing a balloon into the external carotid artery, and occluding flow in the external carotid artery.

Claim 12 further has been amended to recite that the occlusion element is configured to extend beyond the distal end of the catheter and form a tapered entrance to the lumen of the catheter, so that when expanded the occlusion element forms a funnel-shape that inhibits aggregation of emboli between a wall of the proximal segment and the distal end of the catheter. Importantly, as recited in amended claim 12, this feature enables blood aspirated from the region of the bifurcation and the internal carotid artery to remove substantially all emboli liberated from the stenosis.

Amended claim 12 plainly differs from the devices disclosed in the Solano reference discussed at pages 3-4 of the specification, which do not teach or suggest the use of a separate balloon on a wire to occlude flow reversal in the external carotid artery. Indeed, Solano does not even appear to appreciate that flow reverses in the external carotid artery and flows into the internal carotid artery when the occlusion element of the catheter is deployed.

Amended claim 12 also patentably distinguishes over the systems disclosed in EP Publication No. 0 427 429 and the chapter from Interventional Neuroradiology, discussed at page 5 of the specification, because the occlusion elements of the catheters described in those reference are affixed proximal of the distal end of the catheter, do not form a tapered entrance to the lumen of the catheter. It is therefore believed that

debris may aggregate around the distal tips of the catheters, so that those devices cannot remove substantially all emboli liberated from the stenosis.

In addition, in view of problems inherent in the foregoing prior art systems, as described at pages 5 through 7 of the specification of the present application, applicant respectfully submits that his solution would not have been obvious to one of ordinary skill in the art, but only by hindsight gleaned from applicant's own disclosure. In this regard, applicant submits that it should be accorded a standard of obviousness that is not substantially out of proportion to that applied to its competitors. See, for example, the claims of U.S. Patent No. 6,533,800 (copy enclosed), recently issued to one of applicant's competitors over substantially the same prior art as is of record in this case.*

With respect to double patenting, applicant submits that claim 12 is directed to a different invention than claim 15 of the '032 patent, in that claim 12 does not require the presence of the venous return catheter. Moreover, claim 12 recites method steps directed specifically to placement of the components of the device relative to the junction of the common carotid artery, the internal carotid artery and the external carotid artery. Claim 12 also recites that aspiration of blood from the region removes substantially all emboli from the region, a limitation not required in claim 15 or any of the other method claims of the '032 patent.

Applicant submits that claims 13, 15 and 18-20 are patentable for at least the same reasons as amended claim 12.

---

* Applicant notes that this patent is ***not*** prior art to the present application, and has an effective filing date more than several years later than the present application.

New independent claim 25 recites steps of inserting a vessel having a proximal segment and first and second distal segments, expanding an occlusion device to reverse flow from the second segment to the first segment, inserting a venous return catheter into a remote vein, ***communicating a pressure differential between the proximal segment and the remote vein through the lumen of the catheter and the lumen of the venous return catheter to aspirate blood from the proximal segment and induce reversal of flow through at least the first segment***, and reinfusing aspirated blood to the remote vein via the venous return catheter.

None of the cited prior art teaches or suggest the use of physiologic pressure gradients between the arterial and venous systems to induce flow reversal in the first segment, and none provides a physiologically limited flow rate that avoids potential trauma to the vessels as described at page 7, line 23 to page 9, line 14. The references described above, such as Solano and the EP Publication, do not filter or reinfuse aspirated blood at all, and in fact may result in either inadequate blood removal or excessive blood loss.

On the other hand, the Imran reference, discussed at pages 7-9 of the specification, like the Valley and Stevens references cited by the Examiner, all rely upon suction created by an external pump to induce flow reversal. Because the retrograde flow induced in the vessels is not physiologically mediated by naturally occurring pressure gradients in the patient's body, these prior art devices all are susceptible to unsustainably high flow rates, vessel trauma, excessive blood loss and/or hemodilution, and unacceptably low blood pressure.

With respect to double patenting, applicant submits that claim 25 is directed to a different invention than claim 15 of the '032 patent, in that does not require that the occlusion

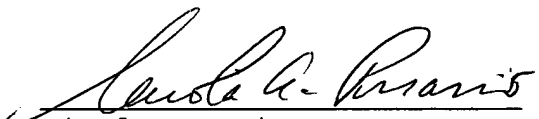
element define a tapered entrance to the catheter, as recited in claim 15. Moreover, new claim 25 recites a step of communicating a pressure differential between the proximal segment and the remote vein through the lumen of the catheter and the lumen of the venous return catheter to aspirate blood from the proximal segment and induce reversal of flow through at least the first segment, a limitation not required in claim 15 or any of the other method claims of the '032 patent.

Applicant submits that claims 26-32 are patentably for at least the same reasons as claim 25.

CONCLUSION

In view of the foregoing, applicants respectfully submit that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,



Nicola A. Pisano
Registration No: 34,408
Attorney for Applicant

c/o Luce, Forward,
Hamilton & Scripps, LLP
11988 El Camino Real, Suite 200
San Diego, California 92130
Tel.: 858.720.6320

1930407.1